ABBOTT

Corporate Regulatory Affairs

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August 23, 1999

Dockets Management Branch (HFA-305)
The Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20857

RE: Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions
[Docket No. 99N-1737]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

I. GENERAL REMARKS

1. HIMA. Abbott generally supports the August 23, 1999 response to this same subject sent to the FDA by the Health Industry Manufacturers Association (HIMA).

2. Access by Individuals and Overall Goals Support. One purpose of Section 113 of FDAMA is "to simplify the process through which individuals with serious or life-threatening medical conditions obtain information about opportunities to participate in clinical trials of experimental therapies." While we endorse this goal, there are two other goals which must also be supported, namely, (1) maintaining the integrity of the clinical trials process, and (2) protecting the competitive advantages of those medical device firms involved in clinical research.

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3. Experience from the Drug Database. One intent of Congress was that the FDA and other government agencies get at least two years' experience with the drug data bank for clinical trials before proceeding with the device clinical trials database. While the drug data bank has yet to be established, we believe that experience with the database for drugs would be a worthwhile consideration in designing and developing a clinical trials database for medical devices. It would be best to wait, however, until all parties gain experience and knowledge operating the drug database.

4. Development and Communication. We recommend a series of ongoing discussions and communications between the Agency, industry and other parties concerning the development of any device clinical trials database. A key consideration in the development process is how the database would accomplish many of the following potentially conflicting objectives:

   - Be accountable to individuals yet maintain privacy on a national level.
   - Meet broad national objectives such as FDAMA but also remain accessible to all parties, including those who may not have access to the Internet.
   - Stimulate individuals to participate yet maintain the privacy and technical advantage of the company conducting the research.

II. SPECIFIC COMMENTS

The FDA asked for comments on eight specific question. The questions and our comments are shown below:

1. *Is there a public health need for inclusion of device investigations within the scope of the data bank under 402(j) of the PHS Act?*

   Comment: It is our opinion that a public health need does exist. Several historical examples bear this out. For instance, the many early attempts to develop an artificial heart and associated replacement parts were hindered due to a lack of suitable patients. Similarly, early tests on many of today's commonly used devices for cardiovascular surgery had to be delayed or taken overseas due to the inability to attract and identify suitable candidates for human trials. Finally, we must recognize that these trials may be the only potential source of help for some patients.

2. A. *If there is a public health need, what category of device trials should be made publicly available and how should this category be defined?*

   Comment: We would recommend that trials involving the more critical or life-dependent devices be made publicly available. This typically includes Class III and PMA-type devices.

   B. *FDA's treatment IDE regulation applies only to devices for which no comparable or satisfactory alternative exists. Should a data bank for IDE's be similarly restricted?*

   Comment: No. We would encourage the Agency to act positively on these provisions and not to "restrict" any information other than to blind selected data. Certain data must be blinded so that original research is not compromised and company identification remains known only to the Agency.

   The Agency should not restrict this work to treatment IDE's since it would limit the intent of FDAMA; it would limit the availability of potentially life-enhancing procedures to the public; and it would prevent the identification of suitable candidates, a major factor in preserving national competitiveness.

   C. *Should the trials that become part of the data bank include feasibility/pilot trials or only studies that are intended to demonstrate reasonable assurance of safety and effectiveness?*

   Comment: The FDA should use its scientific knowledge base to resolve this question. Historically, pilot testing has been closely controlled when humans are involved so as to prevent unintended harm to healthy subjects. When the device has shown some degree of reliability, only then should the trials be made public through this proposed database.

3. *Investigational device trials have historically been smaller in numbers of subjects and numbers of investigational sites than investigational drug trials. What impact, both positive and negative, would the release of information have on these device trials, the sponsors, the investigators, the investigational sites, and the patients?*

   Comment: Historically the FDA has closely controlled these trials, including the associated statistical rationales for selecting population and sample sizes. We would not expect the FDA to change this oversight function despite a wider public awareness of the many ongoing device clinical trials. Nevertheless, certain impacts could be experienced by all parties involved with device clinical trials if, or when they are generally better known to the public.

   Positive Impact: Both the public and the Agency would have greater assurance that the device in question is safe since the clinical trials could be carried out with a larger and perhaps a more statistically significant population and related sample size.

   Negative Impacts: If the Agency develops a database as described above, the public's greater desire or ability to participate in a certain trial should still be limited to the formal inclusion criteria as specified in the company's clinical protocol. The other issue is the possible management of a trial in which a limited number of devices are available for life-threatening diseases. For example, a drug company was recently confronted with the necessity of having to run a lottery for including a specific type of patient for a possible cure to a specific type of cancer. This scenario stemmed from a limited supply of the drug used to treat a life-threatening disease.

4. *IDE information is generally protected from public disclosure under FDA regulations. If public disclosure were voluntary, would disclosure by one sponsor put pressure on sponsors of similar investigations to disclose the existence of their studies against their better judgment? Is this in the interest of the public health?*

   Comment: We again defer to a blinding of data by the Agency which would maintain the integrity of research while allowing individuals to pursue specific treatments. The database might be tailored to list treatments and contact persons only. Multiple "hits" or listings under one specific treatment should not compromise the identity of the company. In all cases, competitive advances, specifically related to the overall national competitiveness, must also be maintained.

5. A. *If disclosure is mandatory, is it likely to hamper innovations and investment in research and development?*

   Comment: Yes. The company undertaking the research along with the specific information about the product and possible course of treatment should not be disclosed.

   B. *Would disclosure of these investigational device trials help or hinder research by increasing patient enrollment?*

   Comment: As described in #3, given the potential for larger populations and an increased number of test subjects, the outcomes would be more reliable.

6. A. *Because sponsors can recover some of the costs of the device research and development under the investigational device regulations, should FDA be concerned that publicly available information concerning investigational device trials will result in undue financial pressure or incentives on the trial sponsors to add subjects to the trials without appropriate consideration of risk?*

   Comment: The statistical and ethical principles of the trial must be maintained, and the Agency and the sponsor must communicate their statistical needs and material expectations to one another in these instances.

   B. *Should FDA be concerned about the possibility that improper promotion and commercialization will occur as a result of a public data bank for IDE trials?*

   Comment: This is a possibility if too much data are made available and an uncontrolled format is allowed to be made public. The Agency has already stated that it would consider improper promotion in this format as a basis for possible enforcement actions.

7. *Will public disclosure of information about device trials for products to treat serious or life-threatening disease or conditions affect reimbursement policies of third party payers?*

   Comment: Possibly. But this issue goes beyond FDAMA and should be resolved through joint efforts with HCFA, industry and other parties.

8. *What other important information or issues should the agency consider?*

   Comment: The Agency should consider in what format this information will be displayed and how it will be made available to the public. By providing too much information, research integrity and clinical trial data may be unduly pressured. Issues of competitiveness should be resolved through consultation with industry trade associations and individual companies as this remains a viable concern for this issue. Finally, the Agency should develop operating principles to ensure proper operation of the database including data input, data display, when to remove data and how to maintain confidentiality.

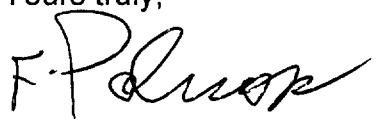
III. CLOSING COMMENTS

The implementation of the proposed database should be undertaken with the following criteria in mind:

A. Consensus based. There exists a real potential for conflicting goals involving private citizens, national companies, various privacy issues and the involvement with companies which vary greatly in size. Because of the broad scope of this proposal, further development on this database should be undertaken with these various parties on a consensus basis.

B. Privacy. Patient confidentiality will be a concern, and in this instance the Agency must also deal with national competitiveness and the proprietary issues affecting the companies carrying out the research.

Yours truly,



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